UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

Richard Barton, Joanna M. Riedl, Nicholas W. Hamilton, David Hornblower and Carla Tomlinson **Plaintiffs,** **Vs.** **LVI Global, LLC, d/b/a Las Vegas Institute, Steve Galella, D.D.S., OrthoMatrix Corp., Inc., also d/b/a Facial Beauty Institute, and John's Dental Laboratory, Inc.** **Defendants.**	**CASE NO:** 1:21-CV-2256

PLAINTIFFS' COMPLAINT

Plaintiffs Richard Barton, Joanna M. Riedl, Nicholas W. Hamilton, David Hornblower, and Carla Tomlinson, by and through their undersigned counsel, by way of Complaint against LVI Global, LLC d/b/a Las Vegas Institute ("LVI"), John's Dental Laboratory, Inc. ("John's Dental"), Steve Gallella, D.D.S., and OrthoMatrix Corp, Inc., also d/b/a as Facial Beauty Institute ("FBI"), hereby allege as follows:

PARTIES

1. Plaintiff Richard Barton is an individual and citizen of California, residing at 500 West Middlefield Rd., #79, Mountain View, California. His claims arise from the laws of Indiana and California.

2. Plaintiff Joanna Riedl is an individual and citizen of Canada, with an address at 1241 Winding Trail, Mississauga, Ontario, Canada. Her claims arise from the laws of Indiana and Alberta and Ontario, Canada.

3. Plaintiff Nicholas W. Hamilton is an individual and citizen of Virginia with an address at 3143 Jupiter Lane, Falls Church, Virginia. His claims arise from the laws of Indiana and Virginia.

4. Plaintiff David Hornblower is a citizen of Canada with an address at 1260 Glen Douglas Drive, Sarnia, Ontario, Canada. His claims arise from the laws of Indiana and Ontario, Canada.

5. Plaintiff Carla Tomlinson is an individual and citizen of Australia with an address at 140 Patricks Road, Arana Hill, Queensland, Australia. Her claims arise from the laws of Indiana and Queensland, Australia.

6. At all times relevant, defendant LVI was a Nevada limited liability company and a citizen of Nevada with a principal place of business located at 1401 Hillshire Dr. in Las Vegas, Nevada 89134.

7. At all times relevant, defendant John's Dental was an Indiana Corporation and citizen of Indiana with a principal place of business at 423 South 13th Street in Terre Haute, Indiana, 47807.

8. At all relevant times, defendant Dr. Steve Galella, D.D.S. ("Dr. Galella) was an individual and a citizen of Tennessee residing at 997 Eastwood Terrace, Collierville, Tennessee 38017.

9. At all relevant times, defendant OrthoMatrix Corp., Inc. ("OrthoMatrix"), d/b/a Facial Beauty Institute ("FBI") and d/b/a as OrthoLogic, was a foreign corporation organized

under the laws of the State of Tennessee, and a citizen of Tennessee, with a principal place of business at 875 West Poplar Avenue, Suite 16, Collierville, Tennessee 38017. FBI is a wholly owned division and/or tradename of defendant OrthoMatrix.

PERSONAL JURISDICTION

10. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. Section 1332 in that all of the plaintiffs are citizens of different states than each of the defendants.

11. The amount in controversy is in excess of Seventy-Five Thousand Dollars ($75,000.00) per plaintiff.

12. Pursuant to 28 U.S.C. 1391, venue is properly laid in this district because a substantial part of the transactions and issues giving rise to plaintiffs' claims occurred in this judicial district.

13. This Court has personal jurisdiction over John's Dental because John's Dental is an Indiana Corporation.

14. This Court has personal jurisdiction over the remaining defendants because they regularly conducted business in Indiana with specific connection to the manufacturing, marketing and sale of the device at issue in this complaint and the claims of plaintiffs.

VENUE

15. Venue is proper in this district because a substantial part of the events or omissions giving rise to the claim occurred in Indiana and because John's Dental is an Indiana entity with a principal place of business in Terre Haute, Indiana.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

NATURE OF THE ACTION

16. This is an action for money damages for personal injury suffered by the plaintiffs as the result of the installation of a dental appliance which defendants designed, manufactured and marketed despite no scientific or clinical basis to prove it was either safe or effective.

17. The appliance, known as an "Anterior Growth Guidance Appliance" ("AGGA") was manufactured, designed, and marketed as a proven means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery.

18. Defendants promoted AGGA, taught dentists how it allegedly functioned, and prepared AGGA treatment plans for dentists, claiming that AGGA causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm, through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate, and that it was a reasonable alternative to jaw surgery.

19. Plaintiffs allege that these claims are false, and are contrary to medical science; that instead AGGA works to push the upper teeth out of their housing in the alveolar bone, that it causes no new bone growth, that it is not a reasonable alternative to jaw surgery, and that it presents a risk of serious and permanent harm.

20. As a result of the fact that AGGA as negligently designed and manufactured was not reasonably safe and was unreasonably dangerous, the promotion and teaching of AGGA involving false representations to dentists including plaintiffs' dentists, the creation of a treatment plan utilizing a product that is unreasonably dangerous, the failure to warn plaintiffs and/or their dentists about the actual risks of AGGA, and the installation of AGGA in plaintiffs have caused plaintiffs to sustain significant and permanent damage to their teeth and face,

economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering.

FACTS ALLEGED

HISTORY OF AGGA

21. At all times relevant to the case, Dr. Galella was a general dentist duly licensed by the State of Tennessee and a diplomate of an organization called the International Board of Orthodontics.

22. Prior to January 2018, Dr. Galella designed the dental appliances called AGGA and the Controlled Arch system of brackets and wires ("CAB").

23. Prior to 2010, Dr. Galella founded FBI, and at all times relevant to the Complaint Dr. Galella and FBI shared office space in Tennessee, along with OrthoMatrix.

24. Prior to 2010, FBI became an unincorporated division and/or trade name of OrthoMatrix.

25. At all times relevant to the Complaint, LVI claimed to be "an international institution dedicated to the progress of the dental profession through the integration of comprehensive diagnosis, contemporary techniques and technology."

26. At all times relevant to the Complaint, LVI further claimed that the "continuing education offered at LVI is designed to improve the lives of patients and enhance professional satisfaction."

27. At all times relevant to the Complaint, Dr. Galella was an officer of, employed by and working in furtherance of the business of, and/or acted as agent of, FBI and, therefore of OrthoMatrix.

28. At all times relevant to the Complaint, LVI, OrthoMatrix, through its division FBI, and Dr. Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB.

29. At all times relevant to the Complaint, OrthoMatrix claimed to be, *inter alia*, a research organization conducting research in various fields including biological mechanisms that cause craniofacial growth in adults.

30. At all times relevant to the Complaint, OrthoMatrix, through its unincorporated division or trade name FBI and/or through another unincorporated division or tradename of OrthoMatrix called OrthoLogic, maintained a program that purported to analyze patients' dental/cranio maxillofacial condition using "radiologists" and "experts" to determine whether said patients were appropriate candidates for AGGA/CAB treatment, and prepare AGGA and CAB treatment plans for such patients with comprehensive instructions that were alleged to be specific and customized for each patient ("the program").

31. Prior to 2010 and at all times relevant to the Complaint, Dr. Galella, LVI, and OrthoMatrix made certain representations ("the representations") to dentists throughout the world, including the dentists who treated the plaintiffs, that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. AGGA is reasonably safe for installation into dental patients' mouths;

g. AGGA can be utilized as a substitute for jaw surgery.

32. Prior to 2010 and at all times relevant to the Complaint, Dr. Galella, LVI, and OrthoMatrix, made additional representations to dentist throughout the world, including to dentists treating plaintiffs, that, once AGGA causes the desired maxilla and mandible position to be obtained, and AGGA was then removed, CAB could be used to make relatively minor adjustments in order to guide all teeth to their proper positions, as well as to widen the dental arches.

33. The representations, made prior to 2010 and at all times relevant to the Complaint by Dr. Galella, LVI, and OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers.

34. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration, or any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

35. Dr. Galella, LVI, and OrthoMatrix, knew or should have known that the representations were unproven, not supported by medical knowledge or science, and were false and materially misleading, and that:

a. AGGA is not a device that can cause changes in the nasomaxillary complex of adults;

b. AGGA is not a device that mechanically causes the maxilla of an adult to move forward horizontally over time as much or more than 10 mm;

c. AGGA does not stimulate new bone growth resulting in changes to the nasomaxillary complex of an adult;

d. AGGA does not move the maxilla; instead, it pushes certain of the upper teeth forward over time within the alveolar bone which is attached to the maxilla;

e. as AGGA pushes the upper teeth forward, the teeth are pushed out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

f. AGGA does not open a user's airway;

g. AGGA is unreasonably dangerous to patients in whom it is installed, and is not reasonably safe for use by such patients; and,

h. AGGA is not a substitute for jaw surgery.

36. At all times relevant to the Complaint, John's Dental was in the business of, *inter alia*, manufacturing, selling and putting into the stream of commerce, dental appliances including but not limited to AGGA and CAB, and was bound to anticipate that their products would be, through dental professionals, presented to the general public for their use, including but not limited to use by consumers within each state of the United States, Queensland, Australia as well as the provinces of Alberta and Ontario, Canada.

37. At all times relevant to the Complaint, John's Dental paid a royalty and/or other fee to both OrthoMatrix and to Galella, or an entity controlled by Galella, for every AGGA device manufactured and sold by John's Dental.

PLAINTIFF RICHARD BARTON

38. Prior to September 2018, dentist Dr. Stephanie Loller ("Dr. Loller") of Inspira Advanced Dentistry in California took a course in the use, safety and efficacy of AGGA at the campus of LVI in Las Vegas, Nevada ("the course").

39. On information and belief, Dr. Loller paid LVI for the course, and the course was approved by LVI and taught by an LVI-approved instructor.

40. During the teaching of the course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

41. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Loller's training concerning AGGA and CAB.

42. Prior to September 2018, Mr. Barton sought treatment from Dr. Loller for obstructive sleep apnea ("OSA"), and Dr. Loller prescribed treatment with an AGGA device for the purpose of opening his airway and alleviating his symptoms.

43. At no time did LVI ever warn Dr. Loller or Mr. Barton that AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

44. Prior to September 2018, Dr. Loller consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Barton was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

45. More specifically, prior to September 2018, on information and belief, Dr. Loller submitted a questionnaire and dental records concerning Mr. Barton to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Mr. Barton ("the treatment plan") and otherwise represented to Dr. Loller and to Mr. Barton that AGGA and CAB were appropriate treatments for Mr. Barton.

46. Prior to September 2018, Dr. Loller, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, Dr. Galella, and LVI, submitted information and/or specifications to John's Dental concerning Mr. Barton and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Mr. Barton.

47. Prior to September 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Loller for installation in Mr. Barton's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Loller, who was then within the State of California; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Loller would install it in Mr. Barton.

48. At the time of sale of the AGGA to Dr. Loller, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Loller, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

49. Mr. Barton reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

50. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Loller for use on Mr. Barton, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Mr. Barton's teeth, and pronounced the AGGA fit to be used.

51. At the time of the sale of the AGGA to Dr. Loller, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Mr. Barton's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery;

b. there is no scientifically valid method of moving an adult maxilla forward more than a de minimis amount without jaw surgery, and there is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy;

c. the design defect of the AGGA was not in any particular component part; but instead was that neither AGGA nor any appliance can possibly do what AGGA claims to have been designed to do;

d. that AGGA is unreasonably dangerous in that, rather than move the maxilla, it pushes the upper teeth forward and out of their proper position within the

alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

e. as AGGA creates substantial risk of harm, and no product can perform the function that it was designed to perform;

f. John's Dental failed to warn Mr. Barton's dentist or anyone else of the defects, deficiencies and dangers of AGGA as set forth in subparts a-e above; and,

g. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Loller the AGGA appliance for Mr. Barton, that appliance was not reasonably safe, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

52. At all times relevant to the Complaint, had Mr. Barton been warned of the defects and deficiencies of AGGA as described above, he would not have embarked on any course of treatment using AGGA.

53. At all times relevant to the Complaint, had Dr. Loller been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, she would not have embarked on any course of treatment of Mr. Barton using AGGA.

54. At all times relevant to the Complaint, Mr. Barton would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

55. By the summer of 2020, Mr. Barton became aware that the AGGA device that had been installed in him was causing severe and permanent injury, and he had the device removed.

56. At all times relevant to the Complaint, Dr. Galella, LVI and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create more than de minimis movement of the human maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to consumers, including but not limited to consumers in the State of California including Mr. Barton; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in the State of California including Mr. Barton.

57. As a result of the installation and use of the AGGA appliances, Mr. Barton has been caused to suffer significant and permanent injury and damage, including but not limited to: degradation and loss of alveolar bone; gum recession; exposure of tooth roots; pain; economic loss related to the cost of said worthless and harmful AGGA treatment; prolonged suffering from OSA as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

58. Mr. Barton at all times relevant to the Complaint acted reasonably, and nothing he did or failed to do caused or contributed to cause his injuries.

COUNT I:

Product Liability-Negligence Against Defendant Dr. Galella

59. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

60. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. negligently designed the AGGA devices that were installed in Mr. Barton, when he knew or should have known that AGGA devices were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton.

61. Dr. Galella acted with reckless disregard for the safety of others, including Mr. Barton.

62. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Mr. Barton, Mr. Barton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT II:

Negligence Against Defendant LVI

63. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

64. LVI was negligent in that, *inter alia,* it:

a. negligently taught or caused to be taught the course to Mr. Barton's dentist, informing her and others that the AGGA device was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton;

b. marketed AGGA to Mr. Barton and to dentists and consumers throughout the world, as a product that was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton; and,

c. negligently failed to warn dentists to whom it taught or caused to be taught the course that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton.

65. LVI acted with reckless disregard for the safety of others, including Mr. Barton.

66. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Mr. Barton, Mr. Barton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT III:

Negligence Against Defendant Orthomatrix And Defendant Galella

67. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

68. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, negligently produced the treatment plan for Mr. Barton's dentist for the installation of an AGGA device on Mr. Barton, when it knew or should have known that said device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton.

69. OrthoMatrix acted with reckless disregard for the safety of others, including Mr. Barton.

70. Galella was negligent in that, *inter alia,* he negligently produced the treatment plan for Mr. Barton's dentist for the installation of an AGGA device on Mr. Barton, when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Barton.

71. Galella acted with reckless disregard for the safety of others, including Mr. Barton.

72. As a direct and proximate result of the negligence of OrthoMatrix and Dr. Galella, and their reckless disregard for the safety of others including Mr. Barton, Mr. Barton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., and defendant Galella, plus interest and costs.

COUNT IV:

Product Liability-Breach Of Warranties Against Defendant John's Dental

73. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

74. At the time that the AGGA devices that were sold to Mr. Barton's dentist last left the possession, custody or control of John's Dental, the devices were inherently defective by virtue of its design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Barton's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above.

75. There is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy such that it would perform the function or functions for which it was designed.

76. When used for the purpose for which it was intended, AGGA presents a risk of serious and permanent injury when used as intended by the designer, manufacturer and seller.

77. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Mr. Barton's dentist and installed in Mr. Barton's mouth.

78. Mr. Barton relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

79. As a direct and proximate result of those breaches of implied warranties, separately and together, Mr. Barton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT V:

Product Liability-Strict Liability Against Defendant John's Dental

80. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

81. At the time the AGGA devices were sold by to John's Dental to Mr. Barton's dentist, the devices were not reasonably safe, were defectively designed and in a condition not reasonably contemplated by Mr. Barton, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury.

82. At the time the AGGA devices were sold by John's Dental to Mr. Barton's dentist, there was no alternative design available to achieve the design function of the products,

as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

83. At the time the AGGA devices were sold by John's Dental to Mr. Barton's dentist, the products posed a substantial likelihood of harm to Mr. Barton or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Barton as a result of the use of the product.

84. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

85. The defective design of the AGGA devices installed in Mr. Barton's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT VI:

Product Liability- Negligence Against Defendant John's Dental

86. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

87. At the time the AGGA devices were sold by to John's Dental to Mr. Barton's dentist John's Dental knew or should have known that the devices were not reasonably safe,

were negligently designed and in a condition not reasonably contemplated by Mr. Barton, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury.

88. At the time the AGGA devices were sold by John's Dental to Mr. Barton's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

89. At the time the AGGA devices were sold by John's Dental to Mr. Barton's dentist, the products posed a substantial likelihood of harm to Mr. Barton or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Barton as a result of the use of the product.

90. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

91. The negligent and defective design of the AGGA devices installed in Mr. Barton's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Richard Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT VII:

California Consumer Legal Remedies Act ("CLRA") Against Defendant John's Dental

92. Plaintiff Richard Barton reaffirms and realleges each of the above paragraphs of the complaint as if specifically affirmed and alleged herein.

93. California Consumer Legal Remedies Act ("CLRA"), California Civil Code Section 1750 et seq., makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in California.

94. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including California consumers) directly, and to dentists (including California dentists) for the purpose of enticing consumers (including California consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

95. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

96. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

97. As a direct and proximate result of the material misrepresentations, Mr. Barton allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

98. This conduct of John's Dental has affected and will continue to affect not just Mr. Barton but also consumers at large within the State of California who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

99. This conduct of John's Dental has also affected and will continue to affect California dentists who, based on those misrepresentations, will utilize AGGA on California consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

100. John's Dental, through its material misrepresentations, has violated CLRA, thereby causing Mr. Barton severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Robert Barton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF JOANNA RIEDL

101. Prior to December 13, 2019, dentist Dr. Alex Pavlenko of Edmonton, Alberta, Canada took a course in the use, safety and efficacy of AGGA at the campus of LVI in Las Vegas, Nevada ("the course").

102. On information and belief, Dr. Pavlenko paid LVI for the course, and the course was approved by LVI and taught by an LVI-approved instructor.

103. During the teaching of the course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

104. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Pavlenko's training concerning AGGA and CAB.

105. Prior to December 13, 2019, Ms. Riedl, then living in the province of Alberta, Canada, sought treatment for chronic mouth breathing, headache, fatigue and an underdeveloped maxilla, and was referred through the LVI website to Dr. Pavlenko; Dr. Pavlenko subsequently prescribed an AGGA device as treatment for those conditions/symptoms.

106. At no time did Dr. LVI ever warn Dr. Pavlenko or Ms. Riedl that AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was

unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

107. Prior to December 13, 2019, Dr. Pavlenko consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Riedl was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

108. More specifically, prior to December 13, 2019, on information and belief, Dr. Pavlenko submitted a questionnaire and dental records concerning Ms. Riedl to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Riedl ("the treatment plan") and otherwise represented to Dr. Pavlenko and to Ms. Riedl that AGGA and CAB were appropriate treatments for Ms. Riedl.

109. Prior to December 13, 2019, Dr. Pavlenko, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, Dr. Galella, and LVI, submitted information and/or specifications to John's Dental concerning Ms. Riedl and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Riedl.

110. Prior to December 13, 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Pavlenko for installation in Ms. Riedl's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Pavlenko, who was then within the province of Alberta, Canada, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Pavlenko would install it in Ms. Riedl.

111. At the time of sale of the AGGA to Dr. Pavlenko, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes

for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Pavlenko, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

112. Ms. Riedl reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

113. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Pavlenko for use on Ms. Riedl, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Riedl's teeth, and pronounced the AGGA fit to be used on Ms. Riedl.

114. At the time of sale of the AGGA to Dr. Pavlenko, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Riedl's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery;

b. there is no scientifically valid method of moving an adult maxilla forward more than a de minimis amount without jaw surgery, and there is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy;

c. the design defect of the AGGA alleged by Ms. Riedl was not in any particular component part; but instead was that neither AGGA nor any appliance can possibly do what AGGA claims to have been designed to do;

d. that AGGA is unreasonably dangerous in that, rather than move the maxilla, it pushes the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

e. AGGA creates substantial risk of harm, and no product can perform the function that it was designed to perform;

f. John's Dental failed to warn Ms. Riedl's dentist or anyone else of the defects, deficiencies and dangers of AGGA as set forth in subparts a-e above; and,

g. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Pavlenko the AGGA appliance for Ms. Riedl, that appliance was not reasonably safe, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

115. At all times relevant to the Complaint, had Ms. Riedl been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

116. At all times relevant to the Complaint, had Dr. Pavlenko been warned by any of the defendants of the defects and deficiencies of AGGA as described above, he then, on

information and belief, would not have embarked on any course of treatment of Ms. Riedl using AGGA.

117. At all times relevant to the Complaint, Ms. Riedl would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

118. By the summer of 2020, Ms. Riedl became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she had the device removed by another dental professional in the province of Ontario, where she was by then living.

119. At all times relevant to the Complaint, Dr. Galella, LVI and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create more than de minimis movement of the human maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to consumers, including but not limited to consumers in the provinces of Alberta and Ontario, Canada, including Ms. Riedl; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in the provinces of Alberta and Ontario, Canada including Ms. Riedl.

120. As a result of the installation and use of the AGGA appliances, Ms. Riedl has been caused to suffer significant and permanent injury and damage, including but not limited to: loss of alveolar bone; chronically aching teeth; gum recession; exposure of tooth roots; pain; unstable bite; inability to bite into solid food; difficulty chewing with attendant nerve pain; future loss of various teeth; flaring of the teeth; misalignment of the teeth; gum recession; jaw spasms; emotional distress; economic loss related to the cost of said worthless and harmful AGGA treatment and the cost of attempted remediation; prolonged suffering from the conditions for which she originally sought treatment; emotional distress; embarrassment; disfigurement; and other injuries and damages.

121. Ms. Riedl at all times relevant to the Complaint acted reasonably, and nothing she reasonably did or failed to do caused or contributed to cause her injuries.

COUNT VIII:

Product Liability-Negligence Against Defendant Dr. Galella

122. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

123. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. Negligently designed the AGGA devices that were installed in Ms. Riedl, when he knew or should have known that AGGA devices were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl;

124. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Riedl.

125. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Riedl, Ms. Riedl has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT IX:

Negligence Against Defendant LVI

126. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

127. Defendant LVI was negligent in that, *inter alia,* it:

a. negligently taught or caused to be taught the course to Ms. Riedl's dentist, informing him and others that the AGGA device was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl;

b. negligently marketed AGGA to Ms. Riedl and to dentists and consumers throughout the world, as a product that was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in

contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl; and,

c. failed to warn dentists to whom it taught or caused to be taught the course that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl.

128. LVI acted with reckless disregard for the safety of others, including Ms. Riedl.

129. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Ms. Riedl, Ms. Riedl has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT X:

Negligence Against Defendant Orthomatrix And Defendant Galella

130. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

131. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, produced the treatment plan for Ms. Riedl's dentist for the installation of an AGGA device, when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science,

it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl.

132. OrthoMatrix acted with reckless disregard for the safety of others, including Riedl.

133. Galella was negligent in that, *inter alia,* he produced the treatment plan for Ms. Riedl's dentist for the installation of an AGGA device, when he knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Riedl.

134. Galella acted with reckless disregard for the safety of others, including Riedl.

135. As a direct and proximate result of the negligence of OrthoMatrix, and Galella and their reckless disregard for the safety of others including Ms. Riedl, Ms. Riedl has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc. and defendant Galella, plus interest and costs.

COUNT XI:

Product Liability-Breach Of Warranties Against Defendant John's Dental

136. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

137. At the time that the AGGA devices that were sold to Ms. Riedl's dentist last left the possession, custody or control of John's Dental, the devices were inherently defective by

virtue of its design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Riedl's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above.

138. There is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy such that it would perform the function or functions for which it was designed.

139. When used for the purpose for which it was intended, AGGA presents a risk of serious and permanent injury when used as intended by the designer, manufacturer and seller.

140. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Ms. Riedl's dentist and installed in Ms. Riedl's mouth.

141. Ms. Riedl relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

142. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Riedl has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XII:

Product Liability- Negligence Against Defendant John's Dental

143. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

144. At the time the AGGA devices were sold by to John's Dental to Ms. Riedl's dentist, John's Dental knew or should have known that the devices were not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. Riedl, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and carried substantial risk of serious injury.

145. At the time the AGGA devices were sold by John's Dental to Ms. Riedl's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

146. At the time the AGGA devices were sold by John's Dental to Ms. Riedl's dentist, the products posed a substantial likelihood of harm to Ms. Riedl or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Riedl as a result of the use of the product.

147. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

148. The negligent and defective design of the AGGA devices installed in Ms. Riedl's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XIII:

Alberta Sale of Goods Act ("SGA") and Alberta Consumer Protection Act ("CPA") Against Defendant John's Dental)

149. Plaintiff Joanna Riedl reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

150. The Alberta Sale of Goods Act ("SGA") and The Alberta Consumer Protection Act ("CPA") make unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Canada.

151. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Canadian consumers) directly, and to dentists (including Canadian dentists) for the purpose of enticing consumers (including Canadian consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the

upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

152. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

153. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

154. As a direct and proximate result of the aforementioned material misrepresentations, Ms. Riedl allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

155. This conduct of John's Dental has affected and will continue to affect not just Ms. Riedl but also consumers at large within Canada who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

156. This conduct of John's Dental has also affected and will continue to affect Canadian dentists who, based on those misrepresentations, will utilize AGGA on Canadian

consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

157. John's Dental, through its material misrepresentations, has violated SGA and CPA, thereby causing Ms. Riedl severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Joanna Riedl demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF NICHOLAS W. HAMILTON

158. Prior to August, 2019, dentist Dr. Michael K. Chung ("Dr. Chung") of Oakton, Virginia took a course in the use, safety and efficacy of AGGA at the campus of LVI in Las Vegas, Nevada ("the course").

159. On information and belief, Dr. Chung paid LVI for the course, and the course was approved by LVI and taught by an LVI-approved instructor.

160. During the teaching of the course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA, which representations included those set forth in above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

161. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Chung's training concerning AGGA and CAB.

162. Prior to August, 2019, Dr. Chung prescribed an AGGA device for plaintiff as treatment primarily for a posterior open bite and TMJ issues including chronic pain.

163. At no time did LVI ever warn Dr. Chung or Mr. Hamilton that AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

164. Prior to August, 2019, Dr. Chung consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Hamilton was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

165. More specifically, prior to August, 2019, on information and belief, Dr. Chung submitted a questionnaire and dental records concerning Mr. Hamilton to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others produced an AGGA/CAB treatment plan for Mr. Hamilton ("the treatment plan") and otherwise represented to Dr. Chung and to Mr. Hamilton that AGGA and CAB were appropriate treatments for Mr. Hamilton.

166. Prior to August, 2019, Dr. Chung, on information and belief in reliance on advice and guidance provided by OrthoMatrix, Dr. Galella, and LVI, submitted information and/or specifications to John's Dental concerning Mr. Hamilton and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Mr. Hamilton.

167. Prior to August 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Chung for installation in Mr. Hamilton's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Chung, who was then within the State of Virginia, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Chung would install it in Mr. Hamilton.

168. At the time of sale of the AGGA to Dr. Chung, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Chung, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

169. Mr. Hamilton reasonably relied upon the aforementioned implied warranties of John's Dental, as well as on its skill and judgment.

170. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Chung for use on Mr. Hamilton, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Mr. Hamilton's teeth, and pronounced the AGGA fit to be used on Mr. Hamilton.

171. At the time of sale of the AGGA to Dr. Chung, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Mr. Hamilton's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery;

b. there is no scientifically valid method of moving an adult maxilla forward more than a de minimis amount without jaw surgery, and there is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy;

c. the design defect of the AGGA was not in any particular component part; but instead, was that neither AGGA nor any appliance can possibly do what AGGA claims to have been designed to do;

d. that AGGA is unreasonably dangerous in that, rather than move the maxilla, it pushes the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

e. as AGGA creates substantial risk of harm as aforesaid, and no product can perform the function that it was designed to perform;

f. John's Dental failed to warn Mr. Hamilton's dentist or anyone else of the defects, deficiencies and dangers of AGGA as set forth in subparts a-e above; and,

g. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Chung the AGGA appliance for Mr. Hamilton, that appliance was not reasonably safe, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

172. At all times relevant to the Complaint, had Mr. Hamilton been warned of the defects and deficiencies of AGGA as described above, he would not have embarked on any course of treatment using AGGA.

173. At all times relevant to the Complaint, had Dr. Chung been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Mr. Hamilton using AGGA.

174. At all times relevant to the Complaint, Mr. Hamilton would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

175. By early 2020**,** Mr. Hamilton became aware that the AGGA device that had been installed in him was causing severe and permanent injury, and he had the device removed in January 2020.

176. At all times relevant to the Complaint, Dr. Galella, LVI and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create more than de minimis movement of the human maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to consumers, including but not limited to consumers in the State of Virginia, including Mr. Hamilton; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise

accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in the State of Virginia including Mr. Hamilton.

177. As a result of the installation and use of the AGGA appliances, Mr. Hamilton has been caused to suffer significant and permanent injury and damage, including but not limited to: gum recession; pain; loose teeth; alveolar bone loss; root exposure; emotional distress; economic loss related to the cost of said worthless and harmful AGGA treatment and the cost of attempted remediation; prolonged suffering from the conditions for which he originally sought treatment; embarrassment; disfigurement; and other injuries and damages.

178. Mr. Hamilton at all times relevant to the Complaint acted reasonably, and nothing he reasonably did or failed to do caused or contributed to cause his aforementioned injuries.

COUNT XIV:

Product Liability-Negligence Against Defendant Dr. Galella

179. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

180. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. designed the AGGA devices that were installed in plaintiff, when he knew or should have known that AGGA devices were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton, all as aforesaid;

181. Dr. Galella acted with reckless disregard for the safety of others, including Mr. Hamilton.

182. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Mr. Hamilton, Mr. Hamilton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT XV:

Negligence Against Defendant LVI

183. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

184. LVI was negligent in that, *inter alia,* it:

a. taught or caused to be taught the course to Mr. Hamilton's dentist, informing him and others that the AGGA device was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton;

b. marketed AGGA to Mr. Hamilton and to dentists and consumers throughout the world, as a product that was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that

it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton; and,

c. failed to warn dentists to whom it taught or caused to be taught the course that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton.

185. LVI acted with reckless disregard for the safety of others, including Mr. Hamilton.

186. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Mr. Hamilton, Mr. Hamilton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT XVI:

Negligence Against Defendant OrthoMatrix and Defendant Galella

187. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

188. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, negligently produced the treatment plan for Mr. Hamilton's dentist for the installation of an AGGA device, when it knew or should have known that said device was unproven, it was neither safe nor efficacious, the principles upon which it

allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton;

189. OrthoMatrix acted with reckless disregard for the safety of others, including plaintiff.

190. Galella was negligent in that, *inter alia,* he negligently produced the treatment plan for Mr. Hamilton's dentist for the installation of an AGGA device, when it knew or should have known that said device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hamilton;

191. Galella acted with reckless disregard for the safety of others, including plaintiff.

192. As a direct and proximate result of the negligence of OrthoMatrix, and its reckless disregard for the safety of others including Mr. Hamilton, Mr. Hamilton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., plus interest and costs.

COUNT XVII:

Product Liability-Breach of Warranties Against Defendant John's Dental

193. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

194. At the time that the AGGA devices that were sold to Mr. Hamilton's dentist last left the possession, custody or control of John's Dental, the devices were inherently defective by virtue of their design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Hamilton's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above.

195. There is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy such that it would perform the function or functions for which it was designed.

196. When used for the purpose for which it was intended, AGGA presents a risk of serious and permanent injury when used as intended by the designer, manufacturer and seller.

197. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Mr. Hamilton's dentist and installed in Mr. Hamilton's mouth.

198. Mr. Hamilton relied on the implied warranties in agreeing to the installation of the AGGA devices.

199. As a direct and proximate result of those breaches of implied warranties, separately and together, Mr. Hamilton has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XVIII:

Product Liability-Strict Liability Against Defendant John's Dental

200. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

201. At the time the AGGA devices were sold by to John's Dental to Mr. Hamilton's dentist said devices were not reasonably safe, were defectively designed and in a condition not reasonably contemplated by Mr. Hamilton, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy.

202. At the time the AGGA devices were sold by John's Dental to Mr. Hamilton's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

203. At the time the AGGA devices were sold by John's Dental to Mr. Hamilton's dentist, the products posed a substantial likelihood of harm to Mr. Hamilton or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Hamilton as a result of the use of the product.

204. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

205. The defective design of the AGGA devices installed in Mr. Hamilton's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XIX:

Product Liability- Negligence Against Defendant John's Dental

206. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

207. At the time the AGGA devices were sold by to John's Dental to Mr. Hamilton's dentist, John's Dental knew or should have known that the devices were not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Mr. Hamilton, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury.

208. At the time the AGGA devices were sold by John's Dental to Mr. Hamilton's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

209. At the time the AGGA devices were sold by John's Dental to Mr. Hamilton's dentist, the products posed a substantial likelihood of harm to Mr. Hamilton or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers,

including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Hamilton as a result of the use of the product.

210. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

211. The negligent and defective design of the AGGA devices installed in Mr. Hamilton's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XX:

Virginia Consumer Protection Act § 59.1-196 ("Virginia CPA")
Against Defendant John's Dental

212. Plaintiff Nicholas W. Hamilton reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

213. Virginia Consumer Protection Act § 59.1-196 ("Virginia CPA") makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Virginia.

214. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Virginia consumers) directly, and to dentists (including Virginia dentists) for the purpose of enticing consumers (including Virginia consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

215. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

216. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

217. As a direct and proximate result of the aforementioned material misrepresentations, Mr. Hamilton allowed AGGA to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

218. This conduct of John's Dental has affected and will continue to affect not just Mr. Hamilton but also consumers at large within the state of Virginia who seek to reconfigure their

jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

219. This conduct of John's Dental has also affected and will continue to affect Virginia dentists who, based on those misrepresentations, will utilize AGGA on Virginia consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

220. John's Dental, through its aforementioned material misrepresentations, has violated Virginia CPA, thereby causing Mr. Hamilton severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Nicholas W. Hamilton demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF DAVID HORNBLOWER

221. Prior to April 15, 2019, Dentist Dr. Vasilios Terzis ("Dr. Terzis") of London, Ontario, Canada, took a course in the use, safety and efficacy of AGGA at the campus of LVI in Las Vegas, Nevada ("the course").

222. On information and belief, Dr. Terzis paid LVI for the course, and the course was approved by LVI and taught by an LVI-approved instructor.

223. During the teaching of the course, the agent, servant or employee of LVI who taught it made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

224. On information and belief, the course, which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Terzis's training concerning AGGA and CAB.

225. Prior to April 15, 2019, Dr. Terzis prescribed an AGGA device for Mr. Hornblower as treatment primarily for sleep dysfunction, feeling that his tongue did not fit in his mouth, ear congestion, grogginess in the morning, waking up startled from choking, clicking and popping of the jaw and narrow and constricted arches.

226. At no time did LVI ever warn Dr. Terzis or Mr. Hornblower that AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, presented a risk of serious and permanent injury to consumers.

227. Prior to April 15, 2019, Dr. Terzis consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Mr. Hornblower was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

228. More specifically, prior to April 15, 2019, on information and belief, Dr. Terzis submitted a questionnaire and dental records concerning Mr. Hornblower to OrthoMatrix's Total Diagnostics internet portal, and then Dr. Galella and OrthoMatrix produced an AGGA/CAB treatment plan for Mr. Hornblower ("the treatment plan") and otherwise represented to Dr. Terzis and to Mr. Hornblower that AGGA and CAB were appropriate treatments for Mr. Hornblower.

229. Prior to April 15, 2019, Dr. Terzis, on information and belief in reliance on advice and guidance provided by OrthoMatrix, Dr. Galella, and LVI, submitted information and/or specifications to John's Dental concerning Mr. Hornblower and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use of Mr. Hornblower.

230. Prior to April 15, 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Terzis for installation in Mr. Hornblower's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Terzis, who was then within the province of Ontario, Canada, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Terzis would install it in Mr. Hornblower.

231. At the time of sale of the AGGA to Dr. Terzis, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Terzis, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

232. Mr. Hornblower reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

233. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Terzis for use on Mr. Hornblower, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Mr. Hornblower's teeth, and pronounced the AGGA fit to be used on Mr. Hornblower.

234. At the time of sale of the AGGA to Dr. Terzis, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Mr. Hornblower's mouth, it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery;

b. there is no scientifically valid method of moving an adult maxilla forward more than a de minimis amount without jaw surgery, and there is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy;

c. the design defect of the AGGA alleged by Mr. Hornblower was not in any particular component part; but instead, was that neither AGGA nor any appliance can possibly do what AGGA claims to have been designed to do;

d. that AGGA is unreasonably dangerous in that, rather than move the maxilla, it pushes the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

e. as AGGA creates substantial risk of harm, and no product can perform the function that it was designed to perform;

f. John's Dental failed to warn Dr. Terzis or anyone else of the defects, deficiencies and dangers of AGGA as set forth in subparts a-e above; and,

g. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Terzis the AGGA appliance for Mr. Hornblower, that appliance was not reasonably safe, was not minimally safe for its expected purpose, and was

dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

235. At all times relevant to the Complaint, had Mr. Hornblower been warned of the defects and deficiencies of AGGA as described above, he would not have embarked on any course of treatment using AGGA.

236. At all times relevant to the Complaint, had Dr. Terzis been warned by any of the defendants of the defects and deficiencies of AGGA as described above, then, on information and belief, he would not have embarked on any course of treatment of Mr. Hornblower using AGGA.

237. At all times relevant to the Complaint, Mr. Hornblower would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

238. By February 2021, Mr. Hornblower became aware that the AGGA device that had been installed in him was causing severe and permanent injury, and he had the device removed on or about October 27, 2019.

239. At all times relevant to the Complaint, Dr. Galella, LVI and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create more than de minimis movement of the human maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would

advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to consumers, including but not limited to consumers in the province of Ontario, Canada, including plaintiff; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in the province of Ontario, Canada including Mr. Hornblower.

240. As a result of the installation and use of the AGGA appliances, Mr. Hornblower has been caused to suffer significant and permanent injury and damage, including but not limited to: pain; nerve damage; loose teeth; alveolar bone loss; root exposure; teeth flaring; future loss of various teeth; emotional distress; economic loss related to the cost of said worthless and harmful AGGA treatment and the cost of attempted remediation; prolonged suffering from the conditions for which he originally sought treatment; embarrassment; disfigurement; and other injuries and damages.

241. Mr. Hornblower at all times relevant to the Complaint acted reasonably, and nothing he reasonably did or failed to do caused or contributed to cause his injuries.

COUNT XXI:
Product Liability-Negligence Against Defendant Dr. Galella

242. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

243. Defendant Dr. Galella was negligent in that, *inter alia,* he:

a. negligently designed the AGGA devices that were installed in plaintiff, when he knew or should have known that AGGA devices were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not

supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower;

b. failed to warn purchasers of AGGA and dentists to whom he taught the course and other similar courses that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

244. Dr. Galella acted with reckless disregard for the safety of others, including Mr. Hornblower.

245. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Mr. Hornblower, Mr. Hornblower has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT XXII:

Negligence Against Defendant LVI

246. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

247. LVI was negligent in that, *inter alia,* it:

a. negligently taught or caused to be taught the course to Mr. Hornblower's dentist, informing him and others that the AGGA device was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower;

b. negligently marketed AGGA to Mr. Hornblower and to dentists and consumers throughout the world, as a product that was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower; and,

c. failed to warn dentists to whom it taught or caused to be taught the course that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower.

248. LVI acted with reckless disregard for the safety of others, including Mr. Hornblower.

249. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Mr. Hornblower, Mr. Hornblower has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT XXIII:

Negligence Against Defendant Orthomatrix And Defendant Galella

250. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

251. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic negligently produced the treatment plan for Mr. Hornblower's dentist for the installation of an AGGA device, when it knew or should have known that said device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science; it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower.

252. Defendant OrthoMatrix acted with reckless disregard for the safety of others, including Mr. Hornblower.

253. Galella was negligent in that, *inter alia,* he negligently either directly or by or through its division or trade name FBI and/or OrthoLogic produced the treatment plan for Mr. Hornblower's dentist for the installation of an AGGA device, when it knew or should have known that said device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical

knowledge and science; it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Mr. Hornblower.

254. Defendant Galella acted with reckless disregard for the safety of others, including Mr. Hornblower.

255. As a direct and proximate result of the negligence of OrthoMatrix, and Dr. Galella and their reckless disregard for the safety of others including Mr. Hornblower, Mr. Hornblower has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., plus interest and costs.

COUNT XXIV:

Product Liability-Breach Of Warranties Against Defendant John's Dental

256. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

257. At the time that the AGGA devices that were sold to Mr. Hornblower's dentist last left the possession, custody or control of John's Dental, the devices were inherently defective by virtue of its design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Mr. Hornblower's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the time each left the possession, custody and control of John's Dental, for reasons that were described above.

258. There is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy.

259. When used for the purpose for which it was intended, AGGA presents a risk of serious and permanent injury when used as intended by the designer, manufacturer and seller.

260. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the AGGA devices sold to Mr. Hornblower's dentist and installed in Mr. Hornblower's mouth.

261. Mr. Hornblower relied on the implied warranties in agreeing to the installation of the AGGA devices.

262. As a direct and proximate result of those breaches of implied warranties, separately and together, Mr. Hornblower has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXV:

(Product Liability- Negligence Against Defendant John's Dental

263. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

264. At the time the AGGA devices were sold by to John's Dental to Mr. Hornblower's dentist, John's Dental knew or should have known that the devices were not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Mr. Hornblower, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury.

265. At the time the AGGA devices were sold by John's Dental to Mr. Hornblower's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

266. At the time the AGGA device was sold by John's Dental to Mr. Hornblower's dentist, the product posed a substantial likelihood of harm to Mr. Hornblower or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Mr. Hornblower as a result of the use of the product.

267. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

268. The defective design of the AGGA devices installed in Mr. Hornblower's mouth was the sole and/or substantial cause and/or factor in bringing about his injuries or damages.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXVI:

Ontario Sale of Goods Act ("SGA") and Ontario Consumer Protection Act ("CPA") Against Defendant John's Dental)

269. Plaintiff David Hornblower reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

270. Ontario Sale of Goods Act ("SGA") and Ontario Consumer Protection Act ("CPA") make unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Canada.

271. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to consumers (including Canadian consumers) directly, and to dentists (including Canadian dentists) for the purpose of enticing consumers (including Canadian consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

272. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

273. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

274. As a direct and proximate result of the material misrepresentations, Mr. Hornblower allowed AGGA to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

275. This conduct of John's Dental has affected and will continue to affect not just Mr. Hornblower but also consumers at large within Canada who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

276. This conduct of John's Dental has also affected and will continue to affect Canadian dentists who, based on those misrepresentations, will utilize AGGA on Canadian consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

277. John's Dental, through its material misrepresentations, has violated SGA and CPA, thereby causing Mr. Hornblower severe and permanent injury and damage as described above.

WHEREFORE, plaintiff David Hornblower demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

PLAINTIFF CARLA TOMLINSON

278. Prior to April 24, 2019, dentist Dr. Ann-Maree Cole of Queensland, Australia, was provided instruction by Dr. Galella in the use, safety and efficacy of AGGA. After such instruction, but prior to April 24, 2019, on information and belief, Dr. Cole was provided further instruction in the use, safety and efficacy of AGGA by LVI.

279. On information and belief, Dr. Cole paid OrthoMatrix for the instruction by Dr. Galella, and she paid defendant LVI for LVI instruction which was approved by LVI and taught by an LVI-approved instructor.

280. During the teaching of the courses, Dr. Galella and the agent, servant or employee of LVI who taught the course for LVI, made various representations about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading.

281. On information and belief, the courses, each of which lasted approximately 2.5 days, largely or completely comprised the extent of Dr. Cole's training concerning AGGA and CAB.

282. Prior to April 24, 2019, Ms. Tomlinson sought treatment from Dr. Cole for obstructive sleep apnea and an underbite; Dr. Cole then prescribed an AGGA device as treatment for those conditions/symptoms.

283. At no time did Dr. Galella, OrthoMatrix or LVI ever warn Dr. Cole or Ms. Tomlinson that AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

284. Prior to April 24, 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Cole for installation in Ms. Tomlinson's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Cole, who was then within Queensland, Australia, and John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Cole would install it in Ms. Tomlinson.

285. At the time of sale of the AGGA to Dr. Cole, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Cole, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

286. Ms. Tomlinson reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

287. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Cole for use on Ms. Tomlinson, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Tomlinson's teeth, and pronounced the AGGA fit to be used on Ms. Tomlinson.

288. At the time of sale of the AGGA to Dr. Cole, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Tomlinson's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery;

b. there is no scientifically valid method of moving an adult maxilla forward more than a de minimis amount without jaw surgery, and there is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy;

c. the design defect of the AGGA alleged by Ms. Tomlinson was not in any particular component part; but instead was that neither AGGA nor any appliance can possibly do what AGGA claims to have been designed to do;

d. that AGGA is unreasonably dangerous in that, rather than move the maxilla, it pushes the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

e. as AGGA creates substantial risk of harm, and no product can perform the function that it was designed to perform;

f. John's Dental failed to warn Dr. Cole or anyone else of the defects, deficiencies and dangers of AGGA as set forth in subparts a-e above; and,

g. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Cole the AGGA appliance for Ms. Tomlinson, that appliance was not reasonably safe, was not minimally safe for its expected purpose, and was

dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

289. At all times relevant to the Complaint, had Ms. Tomlinson been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

290. At all times relevant to the Complaint, had Dr. Cole been warned by any of the defendants of the defects and deficiencies of AGGA as described above on information and belief, she would not have embarked on any course of treatment of Ms. Tomlinson using AGGA.

291. At all times relevant to the Complaint, Ms. Tomlinson would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

292. By summer of 2020, Ms. Tomlinson became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she had the device removed by another dental professional.

293. At all times relevant to the Complaint, Dr. Galella, LVI and OrthoMatrix, engaged in consumer-related conduct that was materially misleading in that: 1) each of them made material misrepresentations to dentists through the course and other courses, and through website marketing to both dentists and consumers, to the effect that AGGA was safe and efficacious and was a reasonable and functionally effective alternative to jaw surgery that would create more than de minimis movement of the human maxilla; 2) such material misrepresentations were made with the knowledge and expectation that those dentists would advertise and otherwise offer AGGA as a safe and efficacious treatment alternative to

consumers, including but not limited to consumers in Queensland, Australia, including Ms. Tomlinson; and, 3) such material misrepresentations were made with the knowledge and expectation that members of the general public would ask dentists for AGGA and/or otherwise accept AGGA as a safe and efficacious treatment alternative to jaw surgery, consumers, including but not limited to consumers in Queensland, Australia including Ms. Tomlinson.

294. As a result of the installation and use of the AGGA appliances, Ms. Tomlinson has been caused to suffer significant and permanent injury and damage, including but not limited to: loss of alveolar bone; chronically aching teeth; gum recession; worsened occlusion; economic loss related to the cost of said worthless and harmful AGGA treatment and the cost of attempted remediation; prolonged suffering from the conditions for which she originally sought treatment; embarrassment; disfigurement; and other injuries and damages.

295. Ms. Tomlinson at all times relevant to the Complaint acted reasonably, and nothing she reasonably did or failed to do caused or contributed to cause her injuries.

COUNT XXVII:
Product Liability-Negligence Against Defendant Dr. Galella

296. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

297. Dr. Galella was negligent in that, *inter alia,* he:

a. negligently designed the AGGA devices that were installed in Ms. Tomlinson, when he knew or should have known that AGGA devices were unproven, were neither safe nor efficacious, the principles upon which AGGA allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Tomlinson;

298. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Tomlinson.

299. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Tomlinson, Ms. Tomlinson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Dr. Steve Galella, D.D.S., plus interest and costs.

COUNT XXVIII:
Negligence Against Defendant LVI

300. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

301. LVI was negligent in that, *inter alia,* it:

a. negligently taught or caused to be taught the course to Ms. Tomlinson's dentist, informing her and others that the AGGA device was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Tomlinson;

b. negligently marketed AGGA to Ms. Tomlinson and to dentists and consumers throughout the world, as a product that was safe and efficacious when it knew or should have known that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in

contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Tomlinson;

c. negligently failed to warn dentists to whom it taught or caused to be taught the course that the device was unproven, it was neither safe nor efficacious, the principles upon which it allegedly functioned were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Tomlinson; and,

302. LVI acted with reckless disregard for the safety of others, including Ms. Tomlinson.

303. As a direct and proximate result of the negligence of LVI, and its reckless disregard for the safety of others including Ms. Tomlinson, Ms. Tomlinson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant LVI, plus interest and costs.

COUNT XXIX:

Product Liability-Breach of Warranties Against Defendant John's Dental

304. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

305. At the time that the AGGA devices that were sold to Ms. Tomlinson's dentist last left the possession, custody or control of John's Dental, the devices were inherently defective by virtue of its design, were not fit for their intended purpose nor for the specific purpose for which they were sold for installation in Ms. Tomlinson's mouth, were not of merchantable quality, were not reasonably or minimally safe, and were unreasonably dangerous and defective, all at the

time each left the possession, custody and control of John's Dental, for reasons that were described above.

306. There is no alternative design of AGGA or any of its components that could have over-ridden scientific principles of physiology and anatomy.

307. When used for the purpose for which it was intended, AGGA and presents a risk of serious and permanent injury when used as intended by the designer, manufacturer and seller.

308. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA devices sold to Ms. Tomlinson's dentist and installed in Ms. Tomlinson's mouth.

309. Ms. Tomlinson relied on the implied warranties in agreeing to the installation of the AGGA devices.

310. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Tomlinson has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXX:

Product Liability-Strict Liability Against Defendant John's Dental

311. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

312. At the time the AGGA devices were sold by to John's Dental to Ms. Tomlinson's dentist, the devices were not reasonably safe, were defectively designed and in a condition not

reasonably contemplated by Ms. Tomlinson, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy.

313. At the time the AGGA devices were sold by John's Dental to Ms. Tomlinson's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

314. At the time the AGGA devices were sold by John's Dental to Ms. Tomlinson's dentist, the products posed a substantial likelihood of harm to Ms. Tomlinson or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Tomlinson as a result of the use of the product.

315. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

316. The defective design of the AGGA devices installed in Ms. Tomlinson's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount of in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXXI:

Product Liability- Negligence Against Defendant John's Dental

317. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

318. At the time the AGGA devices were sold by to John's Dental to Ms. Tomlinson's dentist, John's Dental knew or should have known that the devices were not reasonably safe, were negligently designed and in a condition not reasonably contemplated by Ms. Tomlinson, the ultimate user, including for the reasons that the function for which they were designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury.

319. At the time the AGGA devices were sold by John's Dental to Ms. Tomlinson's dentist, there was no alternative design available to achieve the design function of the products, as the function of the products -mechanically causing more than a de minimis movement of the maxilla- is not scientifically possible without jaw surgery.

320. At the time the AGGA devices were sold by John's Dental to Ms. Tomlinson's dentist, the products posed a substantial likelihood of harm to Ms. Tomlinson or any other user and were unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Tomlinson as a result of the use of the product.

321. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to users.

322. The negligent and defective design of the AGGA devices installed in Ms. Tomlinson's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XXXII:

Australian Consumer Law ("ACL") Against Defendant John's Dental

323. Plaintiff Carla Tomlinson reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

324. Australian Consumer Law ("ACL") makes unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Australia.

325. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that it has, in the course of marketing AGGA to consumers (including Australian consumers) directly, and to dentists (including Australian dentists) for the purpose of enticing consumers (including Australian consumers) to use AGGA, represented falsely that:

a. AGGA is a device that mechanically causes the maxilla to move forward over time;

b. that by touching and thereby stimulating a nerve in the upper palate, AGGA causes new bone to grow at the maxillary tuberosity (the most distal aspect of the

upper jaw) and other places, which in turn causes the maxilla to move forward, effectively lengthening the upper jaw;

c. that as the maxilla moves forward, upper teeth move with it;

d. that by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward;

e. that the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face;

f. is reasonably safe for installation into dental patients' mouths; and,

g. can be utilized as a substitute for jaw surgery.

326. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is useless.

327. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

328. As a direct and proximate result of the material misrepresentations, Ms. Tomlinson allowed AGGA to be installed in her mouth, and as a result suffered serious and permanent injury as described above.

329. This conduct of John's Dental has affected and will continue to affect not just Ms. Tomlinson but also consumers at large within Australia who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

330. This conduct of John's Dental has also affected and will continue to affect Australian dentists who, based on those misrepresentations, will utilize AGGA on Australian

consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

331. John's Dental, through its material misrepresentations, has violated ACL, thereby causing Ms. Tomlinson severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Carla Tomlinson demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorney's fees interest and costs.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all Counts so triable.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. For compensatory damages in excess of $100,000.00;
2. For punitive damages in an amount to be proven at trial;
3. For attorney's fees and costs of suit incurred herein;
4. For pre-judgment and post-judgment interest as allowed by law; and
5. For such other and further relief as is appropriate under the circumstances.

Respectfully submitted,

s/Alan C. Milstein
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Dated: **Tuesday, August 17, 2021**